(b)(2) of this section, that was in commercial distribution before May 28, 1976, or that has, on or before March 26, 2019, been found to be substantially equivalent to any electroconvulsive therapy device with an intended use described in paragraph (b)(2) of this section, that was in commercial distribution before May 28, 1976. Any other electroconvulsive therapy device with an intended use described in paragraph (b)(2) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[83 FR 66123, Dec. 26, 2018]

§ 882.5950 Neurovascular embolization device.

(a) *Identification.* A neurovascular embolization device is an intravascular implant intended to permanently occlude blood flow to cerebral aneurysms and cerebral ateriovenous malformations. This does not include cyanoacrylates and other embolic agents, which act by polymerization or precipitation. Embolization devices used in other vascular applications are also not included in this classification, see § 870.3300.

(b) *Classification.* Class II (special controls.) The special control for this device is the FDA guidance document entitled ''Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices.'' For availability of this guidance document, see § 882.1(e).

[69 FR 77900, Dec. 29, 2004]

§ 882.5960 Skull tongs for traction.

(a) *Identification.* Skull tongs for traction is an instrument used to immobilize a patient with a cervical spine injury (e.g., fracture or dislocation). The device is caliper shaped with tips that penetrate the skin. It is anchored to the skull and has a heavy weight attached to it that maintains, by traction, the patient's position.

(b) *Classification.* Class II (performance standards).

§ 882.5970 Cranial orthosis.

(a) *Identification.* A cranial orthosis is a device that is intended for medical purposes to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants from 3 to 18 months of age, with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

(b) *Classification.* Class II (special controls) (prescription use in accordance with § 801.109 of this chapter, biocompatibility testing, and labeling (contraindications, warnings, precautions, adverse events, instructions for physicians and parents)).

[63 FR 40651, July 30, 1998]

§ 882.5975 Human dura mater.

(a) *Identification.* Human dura mater is human pachymeninx tissue intended to repair defects in human dura mater.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled ''Class II Special Controls Guidance Document: Human Dura Mater.'' See § 882.1(e) for the availability of this guidance.

(c) *Scope.* The classification set forth in this section is only applicable to human dura mater recovered prior to May 25, 2005.

[68 FR 70436, Dec. 18, 2003, as amended at 76 FR 36993, June 24, 2011]

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

Subpart A—General Provisions

Subpart B—Obstetrical and Gynecological Diagnostic Devices

Subpart C—Obstetrical and Gynecological Monitoring Devices

Subpart D—Obstetrical and Gynecological Prosthetic Devices

Subpart E—Obstetrical and Gynecological Surgical Devices

Subpart F—Obstetrical and Gynecological Therapeutic Devices

Subpart G—Assisted Reproduction Devices

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l*, 371.

SOURCE: 45 FR 12684, Feb. 26, 1980, unless otherwise noted.

Subpart A—General Provisions

§ 884.1 Scope.

(a) This part sets forth the classification of obstetrical and gynecological devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, an obstetrical and gynecological device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed only in one subpart.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

(e) Guidance documents referenced in this part are available on the Internet at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*.

[52 FR 17740, May 11, 1987, as amended at 68 FR 44415, Aug. 27, 2003; 78 FR 18233, Mar. 26, 2013]

§ 884.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a ''new'' device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

[52 FR 17740, May 11, 1987]

§ 884.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only;

(b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(c) The device is an in vitro device that is intended:

(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

(6) For identifying or inferring the identity of a microorganism directly from clinical material;

(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in § 812.3(k) of this chapter; and

(9) For near patient testing (point of care).

[65 FR 2319, Jan. 14, 2000]

Subpart B—Obstetrical and Gynecological Diagnostic Devices

§ 884.1040 Viscometer for cervical mucus.

(a) *Identification.* A viscometer for cervical mucus is a device that is intended to measure the relative viscoelasticity of cervical mucus collected from a female patient. Measurements of relative viscoelasticity are intended for use as an adjunct in the clinical evaluation of a female with chronic infertility, to determine the time of ovulation and the penetrability of cervical mucus to motile sperm.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 884.9.

[47 FR 14706, Apr. 6, 1982, as amended at 65 FR 2320, Jan. 14, 2000]

§ 884.1050 Endocervical aspirator.

(a) *Identification.* An endocervical aspirator is a device designed to remove tissue from the endocervix (mucous membrane lining the canal of the cervix of the uterus) by suction with a syringe, bulb and pipette, or catheter. This device is used to evaluate endocervical tissue to detect malignant and premalignant lesions.

(b) *Classification.* Class II (performance standards).

§ 884.1060 Endometrial aspirator.

(a) *Identification.* An endometrial aspirator is a device designed to remove materials from the endometrium (the mucosal lining of the uterus) by suction with a syringe, bulb and pipette, or catheter. This device is used to study endometrial cytology (cells).

(b) *Classification.* Class II. The special controls for this device are:

(1) FDA's:

(i) ''Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' '' and

(ii) ''510(k) Sterility Review Guidance of 2/12/90 (K90–1),''

(2) Labeling:

(i) Indication: Only to evaluate the endometrium, and

(ii) Contraindications: Pregnancy, history of uterine perforation, or a recent cesarean section, and

(3) The sampling component is covered within vagina.

[45 FR 12684, Feb. 26, 1980, as amended at 52 FR 17741, May 11, 1987; 65 FR 17146, Mar. 31, 2000]

§ 884.1100 Endometrial brush.

(a) *Identification.* An endometrial brush is a device designed to remove samples of the endometrium (the mucosal lining of the uterus) by brushing its surface. This device is used to study endometrial cytology (cells).

(b) *Classification.* Class II. The special controls for this device are:

(1) FDA's:

(i) ''Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' '' and

(ii) ''510(k) Sterility Review Guidance of 2/12/90 (K90–1),''

(2) Labeling:

(i) Indication: Only to evaluate the endometrium, and

(ii) Contraindications: Pregnancy, history of uterine perforation, or a recent cesarean section, and

(3) Design and testing:

(i) The sampling component is covered within the vagina, and

(ii) For adherence of the bristles and brush head.

[45 FR 12684, Feb. 26, 1980, as amended at 52 FR 17741, May 11, 1987; 65 FR 17146, Mar. 31, 2000]

§ 884.1175 Endometrial suction curette and accessories.

(a) *Identification.* An endometrial suction curette is a device used to remove material from the uterus and from the mucosal lining of the uterus by scraping and vacuum suction. This device is used to obtain tissue for biopsy or for menstrual extraction. This generic type of device may include catheters, syringes, and tissue filters or traps.

(b) *Classification.* Class II (performance standards).

§ 884.1185 Endometrial washer.

(a) *Identification.* An endometrial washer is a device used to remove materials from the endometrium (the

mucosal lining of the uterus) by washing with water or saline solution and then aspirating with negative pressure. This device is used to study endometrial cytology (cells).

(b) *Classification.* Class II. The special controls for this device are:

(1) FDA's:

(i) ''Use of International Organization for Standardization's ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' '' and

(ii) ''510(k) Sterility Review Guidance of 2/12/90 (K90–1),''

(2) Labeling:

(i) Indication: Only to evaluate the endometrium,

(ii) Contraindications: Pregnancy, history of uterine perforation, or a recent cesarean section, and

(iii) Warning: Do not attach to a wall or any external suction, and

(3) Design and Testing:

(i) The sampling component is covered within the vagina, and

(ii) Intrauterine pressure should not exceed 50 millimeters of mercury.

[45 FR 12684, Feb. 26, 1980, as amended at 52 FR 17741, May 11, 1987; 65 FR 17146, Mar. 31, 2000]

§ 884.1300 Uterotubal carbon dioxide insufflator and accessories.

(a) *Identification.* A uterotubal carbon dioxide insufflator and accessories is a device used to test the patency (lack of obstruction) of the fallopian tubes by pressurizing the uterus and fallopian tubes and filling them with carbon dioxide gas.

(b) *Classification.* Class II (performance standards).

§ 884.1425 Perineometer.

(a) *Identification.* A perineometer is a device consisting of a fluid-filled sack for intravaginal use that is attached to an external manometer. The devices measure the strength of the perineal muscles by offering resistence to a patient's voluntary contractions of these muscles and is used to diagnose and to correct, through exercise, uninary incontinence or sexual dysfunction.

(b) *Classification.* Class II (performance standards).

§ 884.1550 Amniotic fluid sampler (amniocentesis tray).

(a) *Identification.* The amniotic fluid sampler (amniocentesis tray) is a collection of devices used to aspirate amniotic fluid from the amniotic sac via a transabdominal approach. Components of the amniocentesis tray include a disposable 3 inch 20 gauge needle with stylet and a 30 cc. syringe, as well as the various sample collection accessories, such as vials, specimen containers, medium, drapes, etc. The device is used at 16–18 weeks gestation for antepartum diagnosis of certain congenital abnormalities or anytime after 24 weeks gestation when used to assess fetal maturity.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

[61 FR 1123, Jan. 16, 1996, as amended at 66 FR 33808, July 25, 2001]

§ 884.1560 Fetal blood sampler.

(a) *Identification.* A fetal blood sampler is a device used to obtain fetal blood transcervically through an endoscope by puncturing the fetal skin with a short blade and drawing blood into a heparinized tube. The fetal blood pH is determined and used in the diagnosis of fetal distress and fetal hypoxia.

(b) *Classification.* Class II (performance standards).

§ 884.1600 Transabdominal amnioscope (fetoscope) and accessories.

(a) *Identification.* A transabdominal amnioscope is a device designed to permit direct visual examination of the fetus by a telescopic system via abdominal entry. The device is used to ascertain fetal abnormalities, to obtain fetal blood samples, or to obtain fetal tissue. This generic type of device may include the following accessories: trocar and cannula, instruments used through an operating channel or through a separate cannula associated with the amnioscope, light source and cables, and component parts.

(b) *Classification.* Class III (premarket approval).

(c) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before January 29, 1987 for any transabdominal amnioscope (fetoscope) and accessories that was in commercial distribution before May 28, 1976, or that has on or before January 29, 1987 been found to be substantially equivalent to a transabdominal amnioscope (fetoscope) and accessories that was in commercial distribution before May 28, 1976. Any other transabdominal amnioscope (fetoscope) and accessories shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[45 FR 12684, Feb. 26, 1980, as amended at 51 FR 39845, Oct. 31, 1986]

§ 884.1630 Colposcope.

(a) *Identification.* A colposcope is a device designed to permit direct viewing of the tissues of the vagina and cervix by a telescopic system located outside the vagina. It is used to diagnose abnormalities and select areas for biopsy. This generic type of device may include a light source, cables, and component parts.

(b) *Classification.* Class II (special controls). The device, when it is a standard colposcope (or colpomicroscope) that uses only a white light source, does not use filters other than a green filter, does not include image analysis software, and is not smartphone-based, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

[45 FR 12684, Feb. 26, 1980, as amended at 84 FR 71816, Dec. 30, 2019]

§ 884.1640 Culdoscope and accessories.

(a) *Identification.* A culdoscope is a device designed to permit direct viewing of the organs within the peritoneum by a telescopic system introduced into the pelvic cavity through the posterior vaginal fornix. It is used to perform diagnostic and surgical procedures on the female genital organs. This generic type of device may include trocar and cannula, instruments used through an operating channel, scope preheaters, light source and cables, and component parts.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for culdoscope accessories that are not part of a specialized instrument or device delivery system; do not have adapters, connectors, channels, or do not have portals for electrosurgical, laser, or other power sources. Such culdoscope accessory instruments include: lens cleaning brush, biopsy brush, clip applier (without clips), applicator, cannula (without trocar or valves), ligature carrier/needle holder, clamp/hemostat/grasper, curette, instrument guide, ligature passing and knotting instrument, suture needle (without suture), retractor, mechanical (noninflatable), snare, stylet, forceps, dissector, mechanical (noninflatable) scissors, and suction/irrigation probe. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

[45 FR 12684, Feb. 26, 1980, as amended at 61 FR 1123, Jan. 16, 1996; 66 FR 38808, July 25, 2001]

§ 884.1660 Transcervical endoscope (amnioscope) and accessories.

(a) *Identification.* A transcervical endoscope is a device designed to permit direct viewing of the fetus and amniotic sac by means of an open tube introduced into the uterus through the cervix. The device may be used to visualize the fetus or amniotic fluid and to sample fetal blood or amniotic fluid. This generic type of device may include obturators, instruments used through an operating channel, light sources and cables, and component parts.

(b) *Classification.* Class II (performance standards).

§ 884.1690 Hysteroscope and accessories.

(a) *Identification.* A hysteroscope is a device used to permit direct viewing of the cervical canal and the uterine cavity by a telescopic system introduced into the uterus through the cervix. It is used to perform diagnostic and surgical

procedures other than sterilization. This generic type of device may include obturators and sheaths, instruments used through an operating channel, scope preheaters, light sources and cables, and component parts.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for hysteroscope accessories that are not part of a specialized instrument or device delivery system; do not have adapters, connectors, channels, or do not have portals for electrosurgical, laser, or other power sources. Such hysteroscope accessory instruments include: lens cleaning brush, cannula (without trocar or valves), clamp/hemostat/grasper, curette, instrument guide, forceps, dissector, mechanical (noninflatable), and scissors. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

[45 FR 12684, Feb. 26, 1980, as amended at 61 FR 1123, Jan. 16, 1996; 66 FR 38808, July 25, 2001]

§ 884.1700 Hysteroscopic insufflator.

(a) *Identification.* A hysteroscopic insufflator is a device designed to distend the uterus by filling the uterine cavity with a liquid or gas to facilitate viewing with a hysteroscope.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for tubing and tubing/filter fits which only include accessory instruments that are not used to effect intrauterine access, e.g., hysteroscopic introducer sheaths, etc.; and single-use tubing kits used for only intrauterine insufflation. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

[45 FR 12684, Feb. 26, 1980, as amended at 61 FR 1124, Jan. 16, 1996; 66 FR 38808, July 25, 2001]

§ 884.1710 Closed loop hysteroscopic insufflator with cutter-coagulator.

(a) *Identification.* A closed loop hysteroscopic insufflator with cutter-coagulator is a prescription device configured for hysteroscopic insufflation, resection, and coagulation. It is used to perform diagnostic and surgical procedures (*i.e.*, resection and coagulation). This device type contains a closed-loop recirculating fluid management system for the controlled delivery of filtered distension fluid. This device type also contains a bipolar radiofrequency device used in conjunction with a hysteroscope for resection and coagulation of intrauterine tissues.

(b) *Classification.* Class II (special controls). The special control(s) for this device are:

(1) The patient-contacting components of the device must be demonstrated to be biocompatible.

(2) Software validation, verification, and hazard analysis must be provided.

(3) Electrical equipment safety, including appropriate thermal and mechanical safety and electromagnetic compatibility (EMC) testing must be performed.

(4) Device components that are labeled sterile must be validated to a sterility assurance level of 10^{-6}.

(5) Shelf-life testing that demonstrates the device packaging maintains sterility and the functionality of the device is maintained following simulated shipping and handling must be provided to support the proposed shelf life.

(6) Non-clinical testing data must demonstrate the performance characteristics of the device. Detailed protocols and the test reports must be provided for each test.

(i) The following tests must be performed for the resection portion of the device:

(A) Mechanical testing to assess critical joint strength.

(B) Device electrode temperature testing.

(C) Coagulation depth testing.

(D) Simulated use testing.

(E) Device durability testing.

(ii) The following tests must be performed for the fluid management portion of the device:

(A) Mechanical testing to assess tensile strength of connections.

(B) Pressure testing that demonstrates the following parameters, including accuracy of the pressure displayed; appropriate detection and response to overpressure conditions; activation of a secondary overpressure relief valve at the maximum safe level; and all accessories within the fluid path meet the pressure requirements.

(C) Fluid delivery volume testing that demonstrates that the maximum fluid volume delivered is below a predefined level.

(D) Flow rate testing.

(E) Simulated use testing.

(F) Filtration testing.

(G) Blood filtration capacity testing.

(H) Tissue collection capacity testing.

(I) Filtrate characterization and testing that demonstrates that the continuous reintroduction of filtrate into the uterus does not pose a safety risk.

(7) Clinician labeling must include:

(i) Specific instructions and the clinical training needed for the safe use of the device.

(ii) Appropriate warnings, precautions, and information related to overpressurization.

(iii) Appropriate EMC information.

(iv) An expiration date/shelf life.

[82 FR 35073, July 28, 2017]

§ 884.1720 Gynecologic laparoscope and accessories.

(a) *Identification.* A gynecologic laparoscope is a device used to permit direct viewing of the organs within the peritoneum by a telescopic system introduced through the abdominal wall. It is used to perform diagnostic and surgical procedures on the female genital organs. This generic type of device may include: Trocar and cannula, instruments used through an operating channel, scope preheater, light source and cables, and component parts.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for gynecologic laparoscope accessories that are not part of a specialized instrument or device delivery system, do not have adapters, connector channels, or do not have portals for electrosurgical, lasers, or other power sources. Such gynecologic laparosope accessory instruments include: the lens cleaning brush, biopsy brush, clip applier (without clips), applicator, cannula (without trocar or valves), ligature carrier/needle holder, clamp/hemostat/grasper, curette, instrument guide, ligature passing and knotting instrument, suture needle (without suture), retractor, mechanical (noninflatable), snare, stylet, forceps, dissector, mechanical (noninflatable), scissors, and suction/irrigation probe. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

[45 FR 12684, Feb. 26, 1980, as amended at 61 FR 1124, Jan. 16, 1996; 66 FR 38808, July 25, 2001]

§ 884.1730 Laparoscopic insufflator.

(a) *Identification.* A laparoscopic insufflator is a device used to facilitate the use of the laparoscope by filling the peritoneal cavity with gas to distend it.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for tubing and tubing/filter kits which include accessory instruments that are not used to effect intra-abdominal insufflation (pneumoperitoneum). The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

[45 FR 12684, Feb. 26, 1980, as amended at 61 FR 1124, Jan. 16, 1996; 66 FR 38809, July 25, 2001]

Subpart C—Obstetrical and Gynecological Monitoring Devices

§ 884.2050 Obstetric data analyzer.

(a) *Identification.* An obstetric data analyzer (fetal status data analyzer) is a device used during labor to analyze electronic signal data obtained from fetal and maternal monitors. The obstetric data analyzer provides clinical diagnosis of fetal status and recommendations for labor management and clinical interventions. This generic type of device may include signal analysis and display equipment, electronic interfaces for other equipment, and power supplies and component parts.

(b) *Classification:* Class III (premarket approval).

(c) *Date PMA or notice of completion of PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before October 3, 2000, for any obstetric data analyzer described in paragraph (a) of this section that was in commercial distribution before May 28, 1976, or that has been found, on or before October 3, 2000, to be substantially equivalent to an obstetric data analyzer described in paragraph (a) of this section that was in commercial distribution before May 28, 1976. Any other obstetric data analyzer described in paragraph (a) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[65 FR 41332, July 5, 2000]

§ 884.2225 Obstetric-gynecologic ultrasonic imager.

(a) *Identification.* An obstetric-gynecologic ultrasonic imager is a device designed to transmit and receive ultrasonic energy into and from a female patient by pulsed echoscopy. This device is used to provide a visual representation of some physiological or artificial structure, or of a fetus, for diagnostic purposes during a limited period of time. This generic type of device may include the following: signal analysis and display equipment, electronic interfaces for other equipment, patient and equipment supports, coupling gel, and component parts. This generic type of device does not include devices used to monitor the changes in some physiological condition over long periods of time.

(b) *Classification.* Class II (performance standards).

§ 884.2600 Fetal cardiac monitor.

(a) *Identification.* A fetal cardiac monitor is a device used to ascertain fetal heart activity during pregnancy and labor. The device is designed to separate fetal heart signals from maternal heart signals by analyzing electrocardiographic signals (electrical potentials generated during contraction and relaxation of heart muscle) obtained from the maternal abdomen with external electrodes. This generic type of device may include an alarm that signals when the heart rate crosses a preset threshold. This generic type of device includes the ''fetal cardiotachometer (with sensors)'' and the ''fetal electrocardiographic monitor.''

(b) *Classification.* Class II (performance standards).

§ 884.2620 Fetal electroencephalographic monitor.

(a) *Identification.* A fetal electroencephalographic monitor is a device used to detect, measure, and record in graphic form (by means of one or more electrodes placed transcervically on the fetal scalp during labor) the rhythmically varying electrical skin potentials produced by the fetal brain.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any fetal electroencephalographic monitor that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a fetal electroencephalographic monitor in commercial distribution before May 28, 1976. Any other fetal electroencephalographic monitor shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[45 FR 12684, Feb. 26, 1980, as amended at 52 FR 17741, May 11, 1987; 61 FR 50708, Sept. 27, 1996]

§ 884.2640 Fetal phonocardiographic monitor and accessories.

(a) *Identification.* A fetal phonocardiographic monitor is a device designed to detect, measure, and record fetal heart sounds electronically, in graphic form, and noninvasively, to ascertain fetal condition during labor. This generic type of device includes the following accessories: signal analysis and display equipment, patient and equipment supports, and other component parts.

(b) *Classification.* Class II (performance standards).

§ 884.2660 Fetal ultrasonic monitor and accessories.

(a) *Identification.* A fetal ultrasonic monitor is a device designed to transmit and receive ultrasonic energy into and from the pregnant woman, usually by means of continuous wave (doppler) echoscopy. The device is used to represent some physiological condition or characteristic in a measured value over a period of time (e.g., perinatal monitoring during labor) or in an immediately perceptible form (e.g., use of the ultrasonic stethoscope). This generic type of device may include the following accessories: signal analysis and display equipment, electronic interfaces for other equipment, patient and equipment supports, and component parts. This generic type of device does not include devices used to image some relatively unchanging physiological structure or interpret a physiological condition, but does include devices which may be set to alarm automatically at a predetermined threshold value.

(b) *Classification.* Class II (performance standards).

§ 884.2675 Fetal scalp circular (spiral) electrode and applicator.

(a) *Identification.* A fetal scalp circular (spiral) electrode and applicator is a device used to obtain a fetal electrocardiogram during labor and delivery. It establishes electrical contact between fetal skin and an external monitoring device by a shallow subcutaneous puncture of fetal scalp tissue with a curved needle or needles. This generic type of device includes nonreusable spiral electrodes and reusable circular electrodes.

(b) *Classification.* Class II (performance standards).

§ 884.2685 Fetal scalp clip electrode and applicator.

(a) *Identification.* A fetal scalp clip electrode and applicator is a device designed to establish electrical contact between fetal skin and an external monitoring device by means of pinching skin tissue with a nonreusable clip. This device is used to obtain a fetal electrocardiogram. This generic type of device may include a clip electrode applicator.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any fetal scalp clip electrode and applicator that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a fetal scalp clip electrode and applicator that was in commercial distribution before May 28, 1976. Any other fetal scalp clip electrode and applicator shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[45 FR 12684, Feb. 26, 1980, as amended at 52 FR 17741, May 11, 1987; 61 FR 50708, Sept. 27, 1996]

§ 884.2700 Intrauterine pressure monitor and accessories.

(a) *Identification.* An intrauterine pressure monitor is a device designed to detect and measure intrauterine and amniotic fluid pressure with a catheter placed transcervically into the uterine cavity. The device is used to monitor intensity, duration, and frequency of uterine contractions during labor. This generic type of device may include the following accessories: signal analysis and display equipment, patient and equipment supports, and component parts.

(b) *Classification.* Class II (performance standards).

§ 884.2720 External uterine contraction monitor and accessories.

(a) *Identification.* An external uterine contraction monitor (i.e., the tokodynamometer) is a device used to monitor the progress of labor. It measures the duration, frequency, and relative pressure of uterine contractions with a transducer strapped to the maternal abdomen. This generic type of device may include an external pressure transducer, support straps, and other patient and equipment supports.

(b) *Classification.* Class II (performance standards).

§ 884.2730 Home uterine activity monitor.

(a) *Identification.* A home uterine activity monitor (HUAM) is an electronic system for at home antepartum measurement of uterine contractions, data transmission by telephone to a clinical setting, and for receipt and display of the uterine contraction data at the clinic. The HUAM system comprises a tocotransducer, an at-home recorder, a modem, and a computer and monitor that receive, process, and display data. This device is intended for use in women with a previous preterm delivery to aid in the detection of preterm labor.

(b) *Classification.* Class II (special controls); guidance document (Class II Special Controls Guidance for Home Uterine Activity Monitors).

[66 FR 14076, Mar. 9, 2001]

§ 884.2740 Perinatal monitoring system and accessories.

(a) *Identification.* A perinatal monitoring system is a device used to show graphically the relationship between maternal labor and the fetal heart rate by means of combining and coordinating uterine contraction and fetal heart monitors with appropriate displays of the well-being of the fetus during pregnancy, labor, and delivery. This generic type of device may include any of the devices subject to §§ 884.2600, 884.2640, 884.2660, 884.2675, 884.2700, and 884.2720. This generic type of device may include the following accessories: Central monitoring system and remote repeaters, signal analysis and display equipment, patient and equipment supports, and component parts.

(b) *Classification.* Class II (performance standards).

§ 884.2800 Computerized Labor Monitoring System.

(a) *Identification.* A computerized labor monitoring system is a system intended to continuously measure cervical dilation and fetal head descent and provide a display that indicates the progress of labor. The computerized labor monitoring system includes a monitor and ultrasound transducers. Ultrasound transducers are placed on the maternal abdomen and cervix and on the fetal scalp to provide the matrix of measurements used to produce the display.

(b) *Classification.* Class II (special controls). The special controls are the FDA guidance document entitled: ''Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Computerized Labor Monitoring Systems.'' See § 884.1(e) for availability of this guidance document.

[72 FR 20227, Apr. 24, 2007]

§ 884.2900 Fetal stethoscope.

(a) *Identification.* A fetal stethoscope is a device used for listening to fetal heart sounds. It is designed to transmit the fetal heart sounds not only through sound channels by air conduction, but also through the user's head by tissue conduction into the user's ears. It does not use ultrasonic energy. This device is designed to eliminate noise interference commonly caused by handling conventional stethoscopes.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

[45 FR 12684, Feb. 26, 1980, as amended at 66 FR 38809, July 25, 2001]

§ 884.2960 Obstetric ultrasonic transducer and accessories.

(a) *Identification.* An obstetric ultrasonic transducer is a device used to apply ultrasonic energy to, and to receive ultrasonic energy from, the body in conjunction with an obstetric monitor or imager. The device converts electrical signals into ultrasonic energy, and vice versa, by means of an assembly distinct from an ultrasonic generator. This generic type of device may include the following accessories: coupling gel, preamplifiers, amplifiers, signal conditioners with their power supply, connecting cables, and component parts. This generic type of device does not include devices used to generate the ultrasonic frequency electrical signals for application.

(b) *Classification.* Class II (performance standards).

§ 884.2980 Telethermographic system.

(a) *Telethermographic system intended for adjunctive diagnostic screening for detection of breast cancer or other uses*—(1) *Identification.* A telethermographic system for adjunctive diagnostic screening for detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(2) *Classification.* Class I (general controls).

(b) *Telethermographic system intended for use alone in diagnostic screening for detection of breast cancer or other uses*—(1) *Identification.* A telethermographic system for use as the sole diagnostic screening tool for detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(2) *Classification.* Class III.

(3) *Date PMA or notice of completion of a PDP is required.* As of the enactment date of the amendments, May 28, 1976, an approval under section 515 of the act is required before the device described in paragraph (b)(1) may be commercially distributed. See § 884.3.

[53 FR 1566, Jan. 20, 1988, as amended at 55 FR 48440, Nov. 20, 1990; 66 FR 46953, Sept. 10, 2001]

§ 884.2982 Liquid crystal thermographic system.

(a) *A nonelectrically powered or an AC-powered liquid crystal thermographic system intended for adjunctive use in diagnostic screening for detection of breast cancer or other uses*—(1) *Identification.* A nonelectrically powered or an AC-powered liquid crystal thermographic system intended for use as an adjunct to physical palpation or mammography in diagnostic screening for detection of breast cancer or other uses is a nonelectrically powered or an AC-powered device applied to the skin that displays the color patterns of heat sensitive cholesteric liquid crystals that respond to temperature variations of the surface of the body. This generic type of device may include patient and equipment supports, a means to ensure thermal contact between the patient's skin and the liquid crystals, component parts, and accessories.

(2) *Classification.* Class I (general controls).

(b) A nonelectrically powered or an AC-powered liquid crystal thermographic system intended for use alone in diagnostic screening for detection of breast cancer or other uses—

(1) *Identification.* A nonelectrically powered or an AC-powered liquid crystal thermographic system intended for use as the sole diagnostic screening tool for detection of breast cancer or other uses is a nonelectrically powered or an AC-powered device applied to the skin that displays the color patterns of heat sensitive cholesteric liquid crystals that respond to temperature variations of the surface of the body. This generic type of device may include image display and recording equipment, patient and equipment supports, a means to ensure thermal contact between the patient's skin and the liquid crystals, component parts, and accessories.

(2) *Classification.* Class III.

(3) *Date PMA or notice of completion of a PDP is required.* As of the enactment date of the amendments, May 28, 1976, an approval under section 515 of the act is required before the device described in paragraph (b)(1) may be commercially distributed. See § 884.3.

[53 FR 1566, Jan. 20, 1988, as amended at 55 FR 48441, Nov. 20, 1990; 66 FR 46953, Sept. 10, 2001]

§ 884.2990 Breast lesion documentation system.

(a) *Identification.* A breast lesion documentation system is a device for use in producing a surface map of the breast as an aid to document palpable breast lesions identified during a clinical breast examination.

(b) *Classification.* Class II (special controls). The device, when it is a breast examination recording sheet, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9. The special control is FDA's guidance entitled ''Class II Special Controls Guidance Document: Breast Lesion Documentation System.'' See § 884.1(e) for the availability of this guidance document.

[68 FR 44415, Aug. 27, 2003, as amended at 84 FR 71816, Dec. 30, 2019]

Subpart D—Obstetrical and Gynecological Prosthetic Devices

§ 884.3200 Cervical drain.

(a) *Identification.* A cervical drain is a device designed to provide an exit channel for draining discharge from the cervix after pelvic surgery.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

[45 FR 12684, Feb. 26, 1980, as amended at 84 FR 71816, Dec. 30, 2019]

§ 884.3575 Vaginal pessary.

(a) *Identification.* A vaginal pessary is a removable structure placed in the vagina to support the pelvic organs and is used to treat conditions such as uterine prolapse (falling down of uterus), uterine retroposition (backward displacement), or gynecologic hernia.

(b) *Classification.* Class II (performance standards).

§ 884.3650 Fallopian tube prosthesis.

(a) *Identification.* A fallopian tube prosthesis is a device designed to maintain the patency (openness) of the fallopian tube and is used after reconstructive surgery.

(b) *Classification.* Class II (performance standards).

§ 884.3900 Vaginal stent.

(a) *Identification.* A vaginal stent is a device used to enlarge the vagina by stretching, or to support the vagina and to hold a skin graft after reconstructive surgery.

(b) *Classification.* Class II (performance standards).

Subpart E—Obstetrical and Gynecological Surgical Devices

§ 884.4050 Gynecologic laparoscopic power morcellation containment system.

(a) *Identification.* A gynecologic laparoscopic power morcellation containment system is a prescription device consisting of an instrument port and tissue containment method that creates a working space allowing for direct visualization during a power morcellation procedure following a laparoscopic procedure for the excision of benign gynecologic tissue that is not suspected to contain malignancy.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The patient-contacting components of the device must be demonstrated to be biocompatible;

(2) Device components that are labeled sterile must be validated to a sterility assurance level of 10^{-6};

(3) Performance data must support shelf life by demonstrating continued sterility of the device or the sterile components, package integrity, and device functionality over the intended shelf life;

(4) Non-clinical performance data must demonstrate that the device meets all design specifications and performance requirements. The following performance characteristics must be tested:

(i) Demonstration of the device impermeability to tissue, cells, and fluids;

(ii) Demonstration that the device allows for the insertion and withdrawal of laparoscopic instruments while maintaining pneumoperitoneum;

(iii) Demonstration that the containment system provides adequate space to perform morcellation and adequate visualization of the laparoscopic instruments and tissue specimen relative to the external viscera;

(iv) Demonstration that intended laparoscopic instruments and morcellators do not compromise the integrity of the containment system; and

(v) Demonstration that intended users can adequately deploy the device, morcellate a specimen without compromising the integrity of the device, and remove the device without spillage of contents;

(5) Training must be developed and validated to ensure users can follow the instructions for use; and

(6) Labeling must include the following:

(i) A contraindication for use in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy;

(ii) Unless clinical performance data demonstrates that it can be removed or modified, a contraindication for removal of uterine tissue containing suspected fibroids in patients who are: Peri- or postmenopausal, or candidates for en bloc tissue removal, for example, through the vagina or via a mini-laparotomy incision;

(iii) The following boxed warning: ''Warning: Information regarding the potential risks of a procedure with this device should be shared with patients. Uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer. The use of this containment system has not been clinically demonstrated to reduce this risk.''

(iv) A statement limiting use of device to physicians who have completed the training program; and

(v) An expiration date or shelf life.

[81 FR 40183, June 21, 2016]

§ 884.4100 Endoscopic electrocautery and accessories.

(a) *Identification.* An endoscopic electrocautery is a device used to perform female sterilization under endoscopic observation. It is designed to coagulate fallopian tube tissue with a probe heated by low-voltage energy. This generic type of device may include the following accessories: electrical generators, probes, and electrical cables.

(b) *Classification.* Class II. The special controls for this device are:

(1) FDA's:

(i) ''Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' ''

(ii) ''510(k) Sterility Review Guidance 2/12/90 (K–90),'' and

(iii) ''Guidance ('Guidelines') for Evaluation of Laproscopic Bipolar and Thermal Coagulators (and Accessories),''

(2) International Electrotechnical Commission's IEC 60601–1–AM2 (1995–03), Amendment 2, ''Medical Electrical Equipment—Part 1: General Requirements for Safety,''

(3) American National Standards Institute/American Association for Medical Instrumentation's HF–18, 1993, ''Electrosurgical Devices,''

(4) Labeling:

(i) Indication: For female tubal sterilization, and

(ii) Instructions for use:

(A) Destroy at least 2 centimeters of the fallopian tubes,

(B) Use a cut or undampened sinusoidal waveform,

(C) Use a minimum power of 25 watts, and

(D) For devices with ammeters: continue electrode activation for 5 seconds after the visual endpoint (tissue blanching) is reached or current flow ceases indicating adequate tissue destruction.

[45 FR 12684, Feb. 26, 1980, as amended at 52 FR 17741, May 11, 1987; 65 FR 17146, Mar. 31, 2000]

§ 884.4120 Gynecologic electrocautery and accessories.

(a) *Identification.* A gynecologic electrocautery is a device designed to destroy tissue with high temperatures by tissue contact with an electrically heated probe. It is used to excise cervical lesions, perform biopsies, or treat chronic cervicitis under direct visual observation. This generic type of device may include the following accessories: an electrical generator, a probe, and electrical cables.

(b) *Classification.* Class II (performance standards).

§ 884.4150 Bipolar endoscopic coagulator-cutter and accessories.

(a) *Identification.* A bipolar endoscopic coagulator-cutter is a device used to perform female sterilization and other operative procedures

under endoscopic observation. It destroys tissue with high temperatures by directing a high frequency electrical current through tissue between two electrical contacts of a probe. This generic type of device may include the following accessories: an electrical generator, probes, and electrical cables.

(b) *Classification.* Class II. The special controls for this device are:

(1) FDA's:

(i) ''Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' ''

(ii) ''510(k) Sterility Review Guidance 2/12/90 (K–90),'' and

(iii) ''Guidance ('Guidelines') for Evaluation of Laproscopic Bipolar and Thermal Coagulators (and Accessories),''

(2) International Electrotechnical Commission's IEC 60601–1–AM2 (1995–03), Amendment 2, ''Medical Electrical Equipment—Part 1: General Requirements for Safety,''

(3) American National Standards Institute/American Association for Medical Instrumentation's HF–18, 1993, ''Electrosurgical Devices,''

(4) Labeling:

(i) Indication: For female tubal sterilization, and

(ii) Instructions for use:

(A) Destroy at least 2 centimeters of the fallopian tubes,

(B) Use a cut or undampened sinusoidal waveform,

(C) Use a minimum power of 25 watts, and

(D) For devices with ammeters: continue electrode activation for 5 seconds after the visual endpoint (tissue blanching) is reached or current flow ceases indicating adequate tissue destruction.

[45 FR 12684, Feb. 26, 1980, as amended at 52 FR 17741, May 11, 1987; 65 FR 17146, Mar. 31, 2000]

§ 884.4160 Unipolar endoscopic coagulator-cutter and accessories.

(a) *Identification.* A unipolar endoscopic coagulator-cutter is a device designed to destroy tissue with high temperatures by directing a high frequency electrical current through the tissue between an energized probe and a grounding plate. It is used in female sterilization and in other operative procedures under endoscopic observation. This generic type of device may include the following accessories: an electrical generator, probes and electrical cables, and a patient grounding plate. This generic type of device does not include devices used to perform female sterilization under hysteroscopic observation.

(b) *Classification.* Class II (performance standards).

§ 884.4250 Expandable cervical dilator.

(a) *Identification.* An expandable cervical dilator is an instrument with two handles and two opposing blades used manually to dilate (stretch open) the cervical os.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any expandable cervical dilator that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to an expandable cervical dilator that was in commercial distribution before May 28, 1976. Any other expandable cervical dilator shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[45 FR 12684, Feb. 26, 1980, as amended at 52 FR 17741, May 11, 1987; 61 FR 50708, Sept. 27, 1996]

§ 884.4260 Hygroscopic Laminaria cervical dilator.

(a) *Identification.* A hygroscopic *Laminaria* cervical dilator is a device designed to dilate (stretch open) the cervical os by cervical insertion of a conical and expansible material made from the root of a seaweed (*Laminaria* digitata or *Laminaria* japonica). The device is used to induce abortion.

(b) *Classification.* Class II (performance standards).

§ 884.4270 Vibratory cervical dilators.

(a) *Identification.* A vibratory cervical dilator is a device designed to dilate

the cervical os by stretching it with a power-driven vibrating probe head. The device is used to gain access to the uterus or to induce abortion, but is not to be used during labor when a viable fetus is desired or anticipated.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any vibratory cervical dilator that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a vibratory cervical dilator that was in commercial distribution before May 28, 1976. Any other vibratory cervical dilator shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[45 FR 12684, Feb. 26, 1980, as amended at 52 FR 17741, May 11, 1987; 61 FR 50708, Sept. 27, 1996]

§ 884.4340 Fetal vacuum extractor.

(a) *Identification.* A fetal vacuum extractor is a device used to facilitate delivery. The device enables traction to be applied to the fetal head (in the birth canal) by means of a suction cup attached to the scalp and is powered by an external vacuum source. This generic type of device may include the cup, hosing, vacuum source, and vacuum control.

(b) *Classification.* Class II (performance standards).

§ 884.4350 Fetal head elevator.

(a) *Identification.* A fetal head elevator is a prescription device consisting of a mechanism that elevates the fetal head to facilitate delivery during a Caesarean section.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The patient-contacting components of the device must be demonstrated to be biocompatible.

(2) Performance data must demonstrate the sterility of patient-contacting components of the device.

(3) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(4) Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Reliability testing of device deployment and retrieval under relevant use conditions must be conducted.

(ii) Testing of the maximum force applied to the fetal head in an anatomic model must be conducted.

(iii) Testing of uniform application of the elevator mechanism on the fetal head must be conducted.

(5) Labeling must include the following:

(i) Contraindication for use in the presence of active genital infection;

(ii) Specific instructions regarding the proper placement and use of the device; and

(iii) A shelf life.

[82 FR 60114, Dec. 19, 2017]

§ 884.4400 Obstetric forceps.

(a) *Identification.* An obstetric forceps is a device consisting of two blades, with handles, designed to grasp and apply traction to the fetal head in the birth passage and facilitate delivery.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

[45 FR 12684, Feb. 26, 1980, as amended at 84 FR 71816, Dec. 30, 2019]

§ 884.4500 Obstetric fetal destructive instrument.

(a) *Identification.* An obstetric fetal destructive instrument is a device designed to crush or pull the fetal body to facilitate the delivery of a dead or anomalous (abnormal) fetus. This generic type of device includes the cleidoclast, cranioclast, craniotribe, and destructive hook.

(b) *Classification.* Class II (performance standards).

§ 884.4520 Obstetric-gynecologic general manual instrument.

(a) *Identification.* An obstetric-gynecologic general manual instrument is one of a group of devices used to perform simple obstetric and gynecologic manipulative functions. This generic type of device consists of the following:

(1) An episiotomy scissors is a cutting instrument, with two opposed shearing blades, used for surgical incision of the vulvar orifice for obstetrical purposes.

(2) A fiberoptic metal vaginal speculum is a metal instrument, with fiberoptic light, used to expose and illuminate the interior of the vagina.

(3) A metal vaginal speculum is a metal instrument used to expose the interior of the vagina.

(4) An umbilical scissors is a cutting instrument, with two opposed shearing blades, used to cut the umbilical cord.

(5) A uterine clamp is an instrument used to hold the uterus by compression.

(6) A uterine packer is an instrument used to introduce dressing into the uterus or vagina.

(7) A vaginal applicator is an instrument used to insert medication into the vagina.

(8) A vaginal retractor is an instrument used to maintain vaginal exposure by separating the edges of the vagina and holding back the tissue.

(9) A gynecological fibroid hook is an instrument used to exert traction upon a fibroid.

(10) A pelvimeter (external) is an instrument used to measure the external diameters of the pelvis.

(b) *Classification.* Class I (general controls). The devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

[45 FR 12684, Feb. 26, 1980, as amended at 54 FR 25052, June 12, 1989; 66 FR 38809, July 25, 2001]

§ 884.4530 Obstetric-gynecologic specialized manual instrument.

(a) *Identification.* An obstetric-gynecologic specialized manual instrument is one of a group of devices used during obstetric-gynecologic procedures to perform manipulative diagnostic and surgical functions (e.g., dilating, grasping, measuring, and scraping), where structural integrity is the chief criterion of device performance. This type of device consists of the following:

(1) An amniotome is an instrument used to rupture the fetal membranes.

(2) A circumcision clamp is an instrument used to compress the foreskin of the penis during circumcision of a male infant.

(3) An umbilical clamp is an instrument used to compress the umbilical cord.

(4) A uterine curette is an instrument used to scrape and remove material from the uterus.

(5) A fixed-size cervical dilator is any of a series of bougies of various sizes used to dilate the cervical os by stretching the cervix.

(6) A uterine elevator is an instrument inserted into the uterus used to lift and manipulate the uterus.

(7) A gynecological surgical forceps is an instrument with two blades and handles used to pull, grasp, or compress during gynecological examination.

(8) A cervical cone knife is a cutting instrument used to excise and remove tissue from the cervix.

(9) A gynecological cerclage needle is a looplike instrument used to suture the cervix.

(10) A hook-type contraceptive intrauterine device (IUD) remover is an instrument used to remove an IUD from the uterus.

(11) A gynecological fibroid screw is an instrument used to hold onto a fibroid.

(12) A uterine sound is an instrument used to determine the depth of the uterus by inserting it into the uterine cavity.

(13) A cytological cervical spatula is a blunt instrument used to scrape and remove cytological material from the surface of the cervix or vagina.

(14) A gynecological biopsy forceps is an instrument with two blades and handles used for gynecological biopsy procedures.

(15) A uterine tenaculum is a hooklike instrument used to seize and hold the cervix or fundus.

(16) An internal pelvimeter is an instrument used within the vagina to measure the diameter and capacity of the pelvis.

(17) A nonmetal vaginal speculum is a nonmetal instrument used to expose the interior of the vagina.

(18) A fiberoptic nonmetal vaginal speculum is a nonmetal instrument, with fiberoptic light, used to expose and illuminate the interior of the vagina.

(b) *Classification.* (1) Class II (special controls). The device, when it is an umbilical clamp with or without a cutter, a uterine tenaculum which is sterile and does not use suction and is intended for single use, a nonmetal vaginal speculum, or a fiberoptic nonmetal vaginal speculum, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

(2) Class I for the amniotome, uterine curette, cervical dilator (fixed-size bougies), cerclage needle, IUD remover, uterine sound, and gynecological biopsy forceps. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

[45 FR 12684, Feb. 26, 1980, as amended at 61 FR 1124, Jan. 16, 1996; 66 FR 38809, July 25, 2001; 84 FR 71816, Dec. 30, 2019]

§ 884.4550 Gynecologic surgical laser.

(a) *Identification.* A gynecologic surgical laser is a continuous wave carbon dioxide laser designed to destroy tissue thermally or to remove tissue by radiant light energy. The device is used only in conjunction with a colposcope as part of a gynecological surgical system. A colposcope is a magnifying lens system used to examine the vagina and cervix.

(b) *Classification.* Class II (performance standards).

§ 884.4900 Obstetric table and accessories.

(a) *Identification.* An obstetric table is a device with adjustable sections designed to support a patient in the various positions required during obstetric and gynecologic procedures. This generic type of device may include the following accessories: patient equipment, support attachments, and cabinets for warming instruments and disposing of wastes.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

[45 FR 12684, Feb. 26, 1980, as amended at 84 FR 71816, Dec. 30, 2019]

§ 884.4910 Specialized surgical instrumentation for use with urogynecologic surgical mesh.

(a) *Identification.* Specialized surgical instrumentation for use with urogynecologic surgical mesh is a prescription device specifically intended for use as an aid in the insertion, placement, fixation, or anchoring of surgical mesh during urogynecologic procedures. These procedures include transvaginal pelvic organ prolapse repair, sacrocolpopexy (transabdominal pelvic organ prolapse repair), and treatment of female stress urinary incontinence. Examples of specialized surgical instrumentation include needle passers and trocars, needle guides, fixation tools, and tissue anchors. This device is not a manual gastroenterology-urology surgical instrument and accessories (§ 876.4730) or a manual surgical instrument for general use (§ 878.4800).

(b) *Classification.* Class II (special controls). The special controls for specialized surgical instrumentation for use with urogynecologic surgical mesh are:

(1) The device must be demonstrated to be biocompatible;

(2) The device must be demonstrated to be sterile and, if reusable, it must be demonstrated that the device can be adequately reprocessed;

(3) Performance data must support the shelf life of the device by demonstrating package integrity and device functionality over the requested shelf life;

(4) Non-clinical performance testing must demonstrate that the device meets all design specifications and performance requirements, and that the device performs as intended under anticipated conditions of use; and

(5) Labeling must include:

(i) Information regarding the mesh design that may be used with the device;

(ii) Detailed summary of the clinical evaluations pertinent to use of the device;

(iii) Expiration date; and

(iv) Where components are intended to be sterilized by the user prior to initial use and/or are reusable, validated methods and instructions for sterilization and/or reprocessing of any reusable components.

[82 FR 1603, Jan. 6, 2017]

Subpart F—Obstetrical and Gynecological Therapeutic Devices

§ 884.5050 Metreurynter-balloon abortion system.

(a) *Identification.* A metreurynter-balloon abortion system is a device used to induce abortion. The device is inserted into the uterine cavity, inflated, and slowly extracted. The extraction of the balloon from the uterus causes dilation of the cervical os. This generic type of device may include pressure sources and pressure controls.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any metreurynter-balloon abortion system that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a metreurynter-balloon abortion system that was in commercial distribution before May 28, 1976. Any other metreurynter-balloon abortion system shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[45 FR 12684, Feb. 26, 1980, as amended at 52 FR 17741, May 11, 1987; 61 FR 50709, Sept. 27, 1996]

§ 884.5070 Vacuum abortion system.

(a) *Identification.* A vacuum abortion system is a device designed to aspirate transcervically the products of conception or menstruation from the uterus by using a cannula connected to a suction source. This device is used for pregnancy termination or menstrual regulation. This type of device may include aspiration cannula, vacuum source, and vacuum controller.

(b) *Classification.* Class II (performance standards).

§ 884.5100 Obstetric anesthesia set.

(a) *Identification.* An obstetric anesthesia set is an assembly of antiseptic solution, needles, needle guides, syringes, and other accessories, intended for use with an anesthetic drug. This device is used to administer regional blocks (e.g., paracervical, uterosacral, and pudendal) that may be used during labor, delivery, or both.

(b) *Classification.* Class II (performance standards).

§ 884.5150 Nonpowered breast pump.

(a) *Identification.* A nonpowered breast pump is a manual suction device used to express milk from the breast.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9, if the device is using either a bulb or telescoping mechanism which does not develop more than 250 mm Hg suction, and the device materials that contact breast or breast milk do not produce cytotoxicity, irritation, or sensitization effects.

[45 FR 12684, Feb. 26, 1980, as amended at 61 FR 1124, Jan. 16, 1996; 66 FR 38809, July 25, 2001]

§ 884.5160 Powered breast pump.

(a) *Identification.* A powered breast pump in an electrically powered suction device used to express milk from the breast.

(b) *Classification.* Class II (performance standards).

§ 884.5200 Hemorrhoid prevention pressure wedge.

(a) *Identification.* A hemorrhoid prevention pressure wedge provides mechanical support to the perianal region during the labor and delivery process. External mechanical support of the

perianal region is intended to help prevent the occurrence of external hemorrhoids associated with vaginal childbirth.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9. The special controls for this device are:

(1) The sale, distribution, and use of this device are restricted to prescription use in accordance with § 801.109 of this chapter.

(2) The labeling must include specific instructions regarding the proper placement and use of the device.

(3) The device must be demonstrated to be biocompatible.

(4) Mechanical bench testing of material strength must demonstrate that the device will withstand forces encountered during use.

(5) Safety and effectiveness data must demonstrate that the device prevents hemorrhoids in women undergoing spontaneous vaginal delivery, in addition to general controls.

[76 FR 21238, Apr. 15, 2011, as amended at 84 FR 71816, Dec. 30, 2019]

§ 884.5210 Pressure wedge for the reduction of cesarean delivery.

(a) *Identification.* A pressure wedge for the reduction of cesarean delivery is a prescription device that provides external mechanical support to the perianal region during the labor and vaginal delivery process. External mechanical support of the perianal region is intended to help reduce the occurrence of cesarean delivery.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The patient contacting materials must be evaluated to be biocompatible.

(2) Nonclinical performance data must demonstrate that the device will not break when subjected to the forces it will be exposed to during labor.

(3) Performance data must validate the sterility of the device.

(4) Performance data must support the shelf life of the device by demonstrating continued sterility and package integrity over the labeled shelf life.

(5) Clinical performance data must be provided that characterizes the rate of skin/tissue trauma.

(6) The labeling must include:

(i) Specific instructions regarding the proper placement and use of the device.

(ii) A shelf life.

[82 FR 61448, Dec. 28, 2017]

§ 884.5225 Abdominal decompression chamber.

(a) *Identification.* An abdominal decompression chamber is a hoodlike device used to reduce pressure on the pregnant patient's abdomen for the relief of abdominal pain during pregnancy or labor.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any abdominal decompression chamber that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to an abdominal decompression chamber that was in commercial distribution before May 28, 1976. Any other abdominal decompression chamber shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[45 FR 12684, Feb. 26, 1980, as amended at 52 FR 17741, May 11, 1987; 61 FR 50709, Sept. 27, 1996]

§ 884.5250 Cervical cap.

(a) *Identification.* A cervical cap is a flexible cuplike receptacle that fits over the cervix to collect menstrual flow or to aid artificial insemination. This generic type of device is not for contraceptive use.

(b) *Classification.* Class II (performance standards).

§ 884.5300 Condom.

(a) *Identification.* A condom is a sheath which completely covers the penis with a closely fitting membrane. The condom is used for contraceptive

and for prophylactic purposes (preventing transmission of sexually transmitted infections). The device may also be used to collect semen to aid in the diagnosis of infertility.

(b) *Classification.* (1) Class II (special controls) for condoms made of materials other than natural rubber latex, including natural membrane (skin) or synthetic.

(2) Class II (special controls) for natural rubber latex condoms. The guidance document entitled ''Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300'' will serve as the special control. See § 884.1(e) for the availability of this guidance document.

[73 FR 66538, Nov. 10, 2008]

§ 884.5310 Condom with spermicidal lubricant.

(a) *Identification.* A condom with spermicidal lubricant is a sheath which completely covers the penis with a closely fitting membrane with a lubricant that contains a spermicidal agent, nonoxynol–9. This condom is used for contraceptive and prophylactic purposes (preventing transmission of venereal disease).

(b) *Classification.* Class II (performance standards).

[47 FR 49022, Oct. 29, 1982]

§ 884.5320 Glans sheath.

(a) *Identification.* A glans sheath device is a sheath which covers only the glans penis or part thereof and may also cover the area in the immediate proximity thereof, the corona and frenulum, but not the entire shaft of the penis. It is indicated only for the prevention of pregnancy and not for the prevention of sexually-transmitted diseases.

(b) *Classification.* Class III (premarket approval).

(c) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before September 12, 2002, for any glans sheath that was in commercial distribution before May 28, 1976, or that has, on or before September 12, 2002, been found to be substantially equivalent to a glans sheath that was in commercial distribution before May 28, 1976. Any other glans sheath shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[59 FR 67187, Dec. 29, 1994, as amended at 67 FR 40849, June 14, 2002]

§ 884.5330 Multiple-use female condom.

(a) *Identification.* A multiple-use female condom is a sheath-like device that lines the vaginal wall and is inserted into the vagina prior to the initiation of coitus. At the conclusion of coitus, the device can be reused. It is indicated for contraception and prophylactic (preventing the transmission of sexually transmitted infections) purposes.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before November 21, 2011, for any female condom that was in commercial distribution before May 28, 1976, or that has, on or before November 21, 2011, been found to be substantially equivalent to any female condom that was in commercial distribution before May 28, 1976. Any other female condom shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[65 FR 31455, May 18, 2000, as amended at 76 FR 50667, Aug. 16, 2011; 83 FR 48714, Sept. 27, 2018]

§ 884.5340 Single-use internal condom.

(a) *Identification.* A single-use internal condom is an over-the-counter sheath-like device that lines the vaginal or anal wall and is inserted into the vagina or anus prior to the initiation of coitus. At the conclusion of coitus, it is removed and discarded. It is indicated for contraception and/or prophylactic (preventing the transmission of sexually transmitted infections) purposes.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must evaluate the following:

(i) Rate of clinical failure of the device and rate of individual failure modes of the device based on an acute failure modes study evaluating the intended use (vaginal and/or anal intercourse); and

(ii) Cumulative pregnancy rate when using the device based on a contraceptive effectiveness study (when the device is indicated for vaginal intercourse).

(2) Viral penetration testing must demonstrate the device is an effective barrier to sexually transmitted infections.

(3) Nonclinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be evaluated:

(i) Mechanical testing must demonstrate the device can withstand forces under anticipated use conditions, include evaluation of tensile, tear, and burst properties of the device; and

(ii) Compatibility testing with personal lubricants must determine whether the physical properties of the device are adversely affected by use of additional lubricants.

(4) The device must be demonstrated to be biocompatible.

(5) Shelf-life testing must demonstrate that the device maintains its performance characteristics and the packaging of the device must maintain integrity for the duration of the shelf-life.

(6) Labeling of the device must include:

(i) Contraceptive effectiveness table comparing typical use and perfect use pregnancy rates with the device to other available methods of birth control;

(ii) Statement regarding the adverse events associated with the device, including potential transmission of infection, adverse tissue reaction, and ulceration or other physical trauma;

(iii) Expiration date; and

(iv) Statement regarding compatibility with additional types of personal lubricants.

[83 FR 48714, Sept. 27, 2018]

§ 884.5350 Contraceptive diaphragm and accessories.

(a) *Identification.* A contraceptive diaphragm is a closely fitting membrane placed between the posterior aspect of the pubic bone and the posterior vaginal fornix. The device covers the cervix completely and is used with a spermicide to prevent pregnancy. This generic type of device may include an introducer.

(b) *Classification.* Class II (performance standards).

§ 884.5360 Contraceptive intrauterine device (IUD) and introducer.

(a) *Identification.* A contraceptive intrauterine device (IUD) is a device used to prevent pregnancy. The device is placed high in the uterine fundus with a string extending from the device through the cervical os into the vagina. This generic type of device includes the introducer, but does not include contraceptive IUD's that function by drug activity, which are subject to the new drug provisions of the Federal Food, Drug, and Cosmetic Act (see § 310.502).

(b) *Classification.* Class III (premarket approval).

(c) [Reserved]

(d) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before August 4, 1986, for any IUD and introducer that was in commercial distribution before May 28, 1976, or that has on or before August 4, 1986, been found to be substantially equivalent to an IUD and introducer that was in commercial distribution before May 28, 1976. Any other IUD and introducer shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[45 FR 12684, Feb. 26, 1980, as amended at 51 FR 16649, May 5, 1986; 85 FR 18443, Apr. 2, 2020]

§ 884.5370 Software application for contraception.

(a) *Identification.* A software application for contraception is a device that provides user-specific fertility information for preventing a pregnancy. This device includes an algorithm that performs analysis of patient-specific data (*e.g.*, temperature, menstrual cycle dates) to distinguish between fertile and non-fertile days, then provides patient-specific recommendations related to contraception.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must demonstrate the contraceptive effectiveness of the software in the intended use population.

(2) Human factors performance evaluation must be provided to demonstrate that the intended users can self-identify that they are in the intended use population and can correctly use the application, based solely on reading the directions for use for contraception.

(3) Software verification, validation, and hazard analysis must be performed. Documentation must include the following:

(i) A cybersecurity vulnerability and management process to assure software functionality; and

(ii) A description of the technical parameters of the software, including the algorithm used to determine fertility status and alerts for user inputs outside of expected ranges.

(4) Labeling must include:

(i) The following warnings and precautions:

(A) A statement that no contraceptive method is 100% effective.

(B) A statement that another form of contraception (or abstinence) must be used on days specified by the application.

(C) Statements of any factors that may affect the accuracy of the contraceptive information.

(D) A warning that the application cannot protect against sexually transmitted infections.

(ii) Hardware platform and operating system requirements.

(iii) Instructions identifying and explaining how to use the software application, including required user inputs and how to interpret the application outputs.

(iv) A summary of the clinical validation study and results, including effectiveness of the application as a standalone contraceptive and how this effectiveness compares to other forms of legally marketed contraceptives.

[84 FR 7995, Mar. 6, 2019]

§ 884.5380 Contraceptive tubal occlusion device (TOD) and introducer.

(a) *Identification.* A contraceptive tubal occlusion device (TOD) and introducer is a device designed to close a fallopian tube with a mechanical structure, e.g., a band or clip on the outside of the fallopian tube or a plug or valve on the inside. The devices are used to prevent pregnancy.

(b) *Classification.* Class III (premarket approval).

(c) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 30, 1987, for any TOD and introducer that was in commercial distribution before May 28, 1976, or that has on or before December 30, 1987, been found to be substantially equivalent to a TOD and introducer that was in commercial distribution before May 28, 1976. Any other TOD and introducer shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[45 FR 12684, Feb. 26, 1980, as amended at 52 FR 36883, Oct. 1, 1987]

§ 884.5390 Perineal heater.

(a) *Identification.* A perineal heater is a device designed to apply heat directly by contact, or indirectly from a radiant source, to the surface of the perineum (the area between the vulva and the anus) and is used to soothe or to help heal the perineum after an episiotomy (incision of the vulvar orifice for obstetrical purposes).

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures

in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

[45 FR 12684, Feb. 26, 1980, as amended at 84 FR 71816, Dec. 30, 2019]

§ 884.5400 Menstrual cup.

(a) *Identification.* A menstrual cup is a receptacle placed in the vagina to collect menstrual flow.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

[45 FR 12684, Feb. 26, 1980, as amended at 84 FR 71816, Dec. 30, 2019]

§ 884.5425 Scented or scented deodorized menstrual pad.

(a) *Identification.* A scented or scented deodorized menstrual pad is a device that is a pad made of cellulosic or synthetic material which is used to absorb menstrual or other vaginal discharge. It has scent (i.e., fragrance materials) added for aesthetic purposes (scented menstrual pad) or for deodorizing purposes (scented deodorized menstrual pad). This generic type of device includes sterile scented menstrual pads used for medically indicated conditions, but does not include menstrual pads treated with added antimicrobial agents or other drugs.

(b) *Classification.* (1) Class I (general controls) for menstrual pads made of common cellulosic and synthetic material with an established safety profile. The devices subject to this paragraph (b)(1) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9. This exemption does not include the intralabial pads and reusable menstrual pads.

(2) Class II (special controls) for scented or scented deodorized menstrual pads made of materials not described in paragraph (b)(1). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

[45 FR 12684, Feb. 26, 1980, as amended at 45 FR 51185, Aug. 1, 1980; 61 FR 67714, Dec. 24, 1996; 66 FR 38809, July 25, 2001; 84 FR 71816, Dec. 30, 2019]

§ 884.5435 Unscented menstrual pad.

(a) *Identification.* An unscented menstrual pad is a device that is a pad made of cellulosic or synthetic material which is used to absorb menstrual or other vaginal discharge. This generic type of device includes sterile unscented menstrual pads used for medically indicated conditions, but does not include menstrual pads treated with scent (i.e., fragrance materials) or those with added antimicrobial agents or other drugs.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9 only when the device is made of common cellulosic and synthetic material with an established safety profile.

[45 FR 12684, Feb. 26, 1980, as amended at 61 FR 67714, Dec. 24, 1996; 65 FR 2320, Jan. 14, 2000; 73 FR 34860, June 19, 2008; 84 FR 71816, Dec. 30, 2019]

§ 884.5460 Scented or scented deodorized menstrual tampon.

(a) *Identification.* A scented or scented deodorized menstrual tampon is a device that is a plug made of cellulosic or synthetic material that is inserted into the vagina and used to absorb menstrual or other vaginal discharge. It has scent (i.e., fragrance materials) added for aesthetic purposes (scented menstrual tampon) or for deodorizing purposes (scented deodorized menstrual tampon). This generic type of device does not include menstrual tampons treated with added antimicrobial agents or other drugs.

(b) *Classification.* Class II (performance standards).

[45 FR 12684, Feb. 26, 1980, as amended at 45 FR 51186, Aug. 1, 1980]

§ 884.5470 Unscented menstrual tampon.

(a) *Identification.* An unscented menstrual tampon is a device that is a plug made of cellulosic or synthetic material that is inserted into the vagina and used to absorb menstrual or other vaginal discharge. This generic type of device does not include menstrual tampons treated with scent (i.e., fragrance

materials) or those with added antimicrobial agents or other drugs.

(b) *Classification.* Class II (performance standards).

§ 884.5900 Therapeutic vaginal douche apparatus.

(a) *Identification.* A therapeutic vaginal douche apparatus is a device that is a bag or bottle with tubing and a nozzle. The apparatus does not include douche solutions. The apparatus is intended and labeled for use in the treatment of medical conditions except it is not for contraceptive use. After filling the therapeutic vaginal douche apparatus with a solution, the patient uses the device to direct a stream of solution into the vaginal cavity.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I if the device is operated by gravity feed. Devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

[45 FR 12684, Feb. 26, 1980, as amended at 61 FR 1124, Jan. 16, 1996; 66 FR 38809, July 25, 2001]

§ 884.5920 Vaginal insufflator.

(a) *Identification.* A vaginal insufflator is a device used to treat vaginitis by introducing medicated powder from a hand-held bulb into the vagina through an open speculum.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

[45 FR 12684, Feb. 26, 1980, as amended at 54 FR 25052, June 12, 1989; 66 FR 38809, July 25, 2001]

§ 884.5940 Powered vaginal muscle stimulator for therapeutic use.

(a) *Identification.* A powered vaginal muscle stimulator is an electrically powered device designed to stimulate directly the muscles of the vagina with pulsating electrical current. This device is intended and labeled for therapeutic use in increasing muscular tone and strength in the treatment of sexual dysfunction. This generic type of device does not include devices used to treat urinary incontinence.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP for a device is required to be filed with the Food and Drug Administration on or before July 12, 2000, for any powered vaginal muscle stimulator for therapeutic use that was in commercial distribution before May 28, 1976, or that has, on or before July 12, 2000, been found to be substantially equivalent to a powered vaginal muscle stimulator that was in commercial distribution before May 28, 1976. Any other powered vaginal muscle stimulator for therapeutic use shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[45 FR 12684, Feb. 26, 1980, as amended at 52 FR 17741, May 11, 1987; 65 FR 19834, Apr. 13, 2000]

§ 884.5960 Genital vibrator for therapeutic use.

(a) *Identification.* A genital vibrator for therapeutic use is an electrically operated device intended and labeled for therapeutic use in the treatment of sexual dysfunction or as an adjunct to Kegel's exercise (tightening of the muscles of the pelvic floor to increase muscle tone).

(b) *Classification.* Class II (performance standards). The device is exempt from the premarket notification procedures in part 807, subpart E, of this chapter subject to the limitations in § 884.9.

[45 FR 12684, Feb. 26, 1980, as amended at 83 FR 29215, June 5, 2018]

§ 884.5970 Clitoral engorgement device.

(a) *Identification.* A clitoral engorgement device is designed to apply a vacuum to the clitoris. It is intended for use in the treatment of female sexual arousal disorder.

(b) *Classification.* Class II (special controls). The special control is a guidance document entitled: ''Guidance for Industry and FDA Reviewers: Class II Special Controls Guidance Document for Clitoral Engorgement Devices.''

[65 FR 47306, Aug. 2, 2000]

§ 884.5980 Surgical mesh for transvaginal pelvic organ prolapse repair.

(a) *Identification.* Surgical mesh for transvaginal pelvic organ prolapse repair is a prescription device intended to reinforce soft tissue in the pelvic floor. This device is a porous implant that is made of synthetic material, non-synthetic material, or a combination of synthetic and non-synthetic materials. This device does not include surgical mesh for other intended uses (§ 878.3300 of this chapter).

(b) *Classification.* Class III (premarket approval).

(c) *Date premarket application approval or notice of completion of a product development protocol is required.* A premarket application approval or notice of completion of a product development protocol for a device is required to be filed with the Food and Drug Administration on or before July 5, 2018, for any surgical mesh described in paragraph (a) of this section that was in commercial distribution before May 28, 1976, or that has, on or before July 5, 2018, been found substantially equivalent to a surgical mesh described in paragraph (a) of this section that was in commercial distribution before May 28, 1976. Any other surgical mesh for transvaginal pelvic organ prolapse repair shall have an approved premarket application or declared completed product development protocol in effect before being placed in commercial distribution.

[81 FR 361, Jan. 5, 2016, as amended at 81 FR 369, Jan. 5, 2016]

Subpart G—Assisted Reproduction Devices

SOURCE: 63 FR 48436, Sept. 10, 1998, unless otherwise noted.

§ 884.6100 Assisted reproduction needles.

(a) *Identification.* Assisted reproduction needles are devices used in in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), or other assisted reproduction procedures to obtain gametes from the body or introduce gametes, zygote(s), preembryo(s) and/or embryo(s) into the body. This generic type of device may include a single or double lumen needle and component parts, including needle guides, such as those used with ultrasound.

(b) *Classification.* Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, design specifications, labeling requirements, biocompatibility testing, and clinical testing).

§ 884.6110 Assisted reproduction catheters.

(a) *Identification.* Assisted reproduction catheters are devices used in in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), or other assisted reproduction procedures to introduce or remove gametes, zygote(s), preembryo(s), and/or embryo(s) into or from the body. This generic type of device may include catheters, cannulae, introducers, dilators, sheaths, stylets, and component parts.

(b) *Classification.* Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, design specifications, labeling requirements, biocompatibility testing, and clinical testing).

§ 884.6120 Assisted reproduction accessories.

(a) *Identification.* Assisted reproduction accessories are a group of devices used during assisted reproduction procedures, in conjunction with assisted reproduction needles and/or assisted reproduction catheters, to aspirate, incubate, infuse, and/or maintain temperature. This generic type of device may include:

(1) Powered aspiration pumps used to provide low flow, intermittent vacuum for the aspiration of eggs (ova).

(2) Syringe pumps (powered or manual) used to activate a syringe to infuse or aspirate small volumes of fluid during assisted reproduction procedures.

(3) Collection tube warmers, used to maintain the temperature of egg (oocyte) collection tubes at or near body temperature. A dish/plate/microscope stage warmer is a device used to maintain the temperature of the egg (oocyte) during manipulation.

(4) Embryo incubators, used to store and preserve gametes and/or embryos at or near body temperature.

(5) Cryopreservation instrumentation and devices, used to contain, freeze, and maintain gametes and/or embryos at an appropriate freezing temperature.

(b) *Classification.* Class II (special controls) (design specifications, labeling requirements, and clinical testing). The device, when it is a simple embryo incubator with only temperature, gas, and humidity control; a syringe pump; a collection tube warmer; a dish/plate/microscope stage warmer; a controlled-rate cryopreservation freezer; or an assisted reproduction laminar flow workstation is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

[45 FR 12684, Feb. 26, 1980, as amended at 84 FR 71816, Dec. 30, 2019; 85 FR 44188, July 22, 2020]

§ 884.6130 Assisted reproduction microtools.

(a) *Identification.* Assisted reproduction microtools are pipettes or other devices used in the laboratory to denude, micromanipulate, hold, or transfer human gametes or embryos for assisted hatching, intracytoplasmic sperm injection (ICSI), or other assisted reproduction methods.

(b) *Classification.* Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, design specifications, labeling requirements, and clinical testing). The device, when the assisted reproduction microtools (pipettes) are manufactured from glass, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

[45 FR 12684, Feb. 26, 1980, as amended at 84 FR 71816, Dec. 30, 2019]

§ 884.6140 Assisted reproduction micropipette fabrication instruments.

(a) *Identification.* Assisted reproduction micropipette fabrication devices are instruments intended to pull, bevel, or forge a micropipette or needle for intracytoplasmic sperm injection (ICSI), in vitro fertilization (IVF) or other similar assisted reproduction procedures.

(b) *Classification.* Class II (special controls) (design specifications, labeling requirements, and clinical testing).

§ 884.6150 Assisted reproduction micromanipulators and microinjectors.

(a) *Identification.* Assisted reproduction micromanipulators are devices intended to control the position of an assisted reproduction microtool. Assisted reproduction microinjectors are any device intended to control aspiration or expulsion of the contents of an assisted reproduction microtool.

(b) *Classification.* Class II (special controls) (design specifications, labeling requirements, and clinical testing). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

[45 FR 12684, Feb. 26, 1980, as amended at 84 FR 71816, Dec. 30, 2019]

§ 884.6160 Assisted reproduction labware.

(a) *Identification.* Assisted reproduction labware consists of laboratory equipment or supplies intended to prepare, store, manipulate, or transfer human gametes or embryos for in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), or other assisted reproduction procedures. These include syringes, IVF tissue culture dishes, IVF tissue culture plates, pipette tips, dishes, plates, and other vessels that come into physical contact with gametes, embryos or tissue culture media.

(b) *Classification.* Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, design specifications, labeling requirements, and clinical testing). The device, when it is a dish or plate intended for general assisted reproduction technology procedures, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

[45 FR 12684, Feb. 26, 1980, as amended at 84 FR 71816, Dec. 30, 2019]

§ 884.6165 Intravaginal culture system.

(a) *Identification.* An intravaginal culture system is a prescription device intended for preparing, holding, and transferring human gametes or embryos during intravaginal in vitro fertilization or intravaginal culture procedures.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must demonstrate the following:

(i) Comfort and retention of the intravaginal culture device;

(ii) Adverse vaginal tissue reactions associated with intravaginal culture;

(iii) Maximum number of gametes and/or embryos that can be placed in a device; and

(iv) Rates of embryo development to the designated stage, implantation rates, clinical pregnancy rates, live birth rates, and any adverse events or outcomes.

(2) Nonclinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be demonstrated:

(i) Mouse embryo assay testing to assess embryotoxicity by evaluating the gamete and embryo-contacting device components effect on the growth and development of mouse embryos to the blastocyst stage;

(ii) Endotoxin testing on gamete and embryo-contacting components of the device;

(iii) Cleaning and disinfection validation of reusable device components;

(iv) Sterility maintenance of the culture media within the device throughout the vaginal incubation period and subsequent embryo extraction; and

(v) Ability of the device to permit oxygen and carbon dioxide exchange between the media contained within the device and the external environment throughout the vaginal incubation period.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Performance data must demonstrate the sterility of the device components intended to be provided sterile.

(5) Shelf life testing must demonstrate that the device maintains its performance characteristics and the packaging of device components labeled as sterile maintain integrity and sterility for the duration of the shelf life.

(6) Labeling for the device must include:

(i) A detailed summary of the clinical testing, including device effectiveness, device-related complications, and adverse events;

(ii) Validated methods and instructions for reprocessing of reusable components;

(iii) The maximum number of gametes or embryos that can be loaded into the device;

(iv) A warning that informs users that the embryo development is first evaluated following intravaginal culture; and

(v) A statement that instructs the user to use legally marketed assisted reproductive technology media that contain elements to mitigate the contamination risk (*e.g.*, antibiotics) and to support continued embryonic development over the intravaginal culture period.

(7) Patient labeling must be provided and must include:

(i) Relevant warnings, precautions, and adverse effects and complications;

(ii) Information on how to use the device;

(iii) The risks and benefits associated with the use of the device; and

(iv) A summary of the principal clinical device effectiveness results.

[81 FR 379, Jan. 6, 2016]

§ 884.6170 Assisted reproduction water and water purification systems.

(a) *Identification.* Assisted reproduction water purification systems are devices specifically intended to generate high quality, sterile, pyrogen-free water for reconstitution of media used for aspiration, incubation, transfer or storage of gametes or embryos for in vitro fertilization (IVF) or other assisted reproduction procedures. These devices may also be intended as the final rinse for labware or other assisted reproduction devices that will contact the gametes or embryos. These devices

also include bottled water ready for reconstitution available from a vendor that is specifically intended for reconstitution of media used for aspiration, incubation, transfer, or storage of gametes or embryos for IVF or other assisted reproduction procedures.

(b) *Classification.* Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, water quality testing, design specifications, labeling requirements, biocompatibility testing, and clinical testing).

§ 884.6180 Reproductive media and supplements.

(a) *Identification.* Reproductive media and supplement are products that are used for assisted reproduction procedures. Media include liquid and powder versions of various substances that come in direct physical contact with human gametes or embryos (including water, acid solutions used to treat gametes or embryos, rinsing solutions, sperm separation media, supplements, or oil used to cover the media) for the purposes of preparation, maintenance, transfer or storage. Supplements are specific reagents added to media to enhance specific properties of the media (e.g., proteins, sera, antibiotics, etc.).

(b) *Classification.* Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, design specifications, labeling requirements, biocompatibility testing, and clinical testing). The device, when it is phosphate-buffered saline used for washing, and short-term handling and manipulation of gametes and embryos; culture oil used as an overlay for culture media containing gametes and embryos; and water for assisted reproduction applications, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

[63 FR 48436, Sept. 10, 1998, as amended at 85 FR 44188, July 22, 2020]

§ 884.6190 Assisted reproductive microscopes and microscope accessories.

(a) *Identification.* Assisted reproduction microscopes and microscope accessories (excluding microscope stage warmers, which are classified under assisted reproduction accessories) are optical instruments used to enlarge images of gametes or embryos. Variations of microscopes and accessories used for these purposes would include phase contrast microscopes, dissecting microscopes and inverted stage microscopes.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

[63 FR 48436, Sept. 10, 1998, as amended at 64 FR 62977, Nov. 18, 1999; 66 FR 38809, July 25, 2001]

§ 884.6195 Assisted Reproduction Embryo Image Assessment System.

(a) *Identification.* An Assisted Reproduction Embryo Image Assessment System is a prescription device that is designed to obtain and analyze light microscopy images of developing embryos. This device provides information to aid in the selection of embryo(s) for transfer when there are multiple embryos deemed suitable for transfer or freezing.

(b) *Classification.* Class II (special controls). The special control(s) for this device are:

(1) Clinical performance testing must demonstrate a reasonable assurance of safety and effectiveness of the device to predict embryo development. Classification performance (sensitivity and specificity) and predictive accuracy (Positive Predictive Value and Negative Predictive Value) must be assessed at the subject and embryo levels.

(2) Software validation, verification, and hazard analysis must be provided.

(3) Non-clinical performance testing data must demonstrate the performance characteristics of the device. Testing must include the following:

(i) Total light exposure and output testing;

(ii) A safety analysis must be performed based on maximum (worst-case) light exposure to embryos, which also includes the safety of the light wavelength(s) emitted by the device;

(iii) Simulated-use testing;

(iv) Mouse Embryo Assay testing to assess whether device operation impacts growth and development of mouse embryos to the blastocyst stage;

(v) Cleaning and disinfection validation of reusable components;

(vi) Package integrity and transit testing;

(vii) Hardware fail-safe validation;

(viii) Electrical equipment safety and electromagnetic compatibility testing; and

(ix) Prediction algorithm reproducibility.

(4) Labeling must include the following:

(i) A detailed summary of clinical performance testing, including any adverse events;

(ii) Specific instructions, warnings, precautions, and training needed for safe use of the device

(iii) Appropriate electromagnetic compatibility information;

(iv) Validated methods and instructions for cleaning and disinfection of reusable components; and

(v) Information identifying compatible cultureware and explain how they are used with the device.

[80 FR 10332, Feb. 26, 2015]

§ 884.6200 Assisted reproduction laser system.

(a) *Identification.* The assisted reproduction laser system is a device that images, targets, and controls the power and pulse duration of a laser beam used to ablate a small tangential hole in, or to thin, the zona pellucida of an embryo for assisted hatching or other assisted reproduction procedures.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Assisted Reproduction Laser Systems.'' See § 884.1(e) for the availability of this guidance document.

[69 FR 77624, Dec. 28, 2004]

PART 886—OPHTHALMIC DEVICES

Subpart A—General Provisions

Subpart B—Diagnostic Devices